REMARKS

Claims 1-80 and 82-83 are pending.[1] Claims 38-80 and 82-83 are withdrawn as being directed to a non-elected invention. Claims 2-4, 7-10, 15, 18-22, 33, and 36 are rejected under 35 U.S.C. § 112, first paragraph, for lack of written description (new matter). Claims 1-11, 13, 16-24, and 28-37 are rejected under 35 U.S.C. § 102(b) for anticipation, or in the alternative under 35 U.S.C. § 103(a) for obviousness, over Wironen et al. (WO 99/38543; hereinafter "Wironen"). Claims 12, 14, and 25-27 are objected to. By this reply, Applicants cancel claims 2, 5, 6, 39, 42, 43, and 83, adds new claims 84-94, amend claims 1, 3, 4, 18-23, 31-38, 40, 41, 47, 55-60, 68-70, 77-80, and 82, and address each of the Examiner's rejections.

Support for the Amendment

Support for the amendment to claims 1, 37, 38, 77, 78, and 80 is found in the specification at, e.g., Table 2, pages 44-45, and page 11, lines 16-21. Support for new claims 84-94 is found in the specification at, e.g., page 35, lines 7-13. Claims 3, 4, 18-23, 31-36, 40, 41, 47, 55-60, 68-70, 79, and 82 are amended for reasons related to clarity. No new matter is added by the amendment.

Information Disclosure Statement

Applicants note that the Form PTO-1449s that were filed with Information Disclosure Statements on May 8, 2007, and May 21, 2007, have not been initialed and returned. Applicants respectfully request that the Examiner initial and return the Form PTO-1449s with the next

[1] Claim 81 was cancelled by an Amendment filed on December 22, 2004; the Amendment was resubmitted as a Reply to Notice of Non-Compliant Amendment on June 15, 2005.

Office Action.

Rejection under 35 U.S.C. § 112, first paragraph

The Office rejects claims 2-4, 7-10, 15, 18-22, 33, and 36 under 35 U.S.C. § 112, first paragraph, for new matter. The Office states that "[t]he claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention" (Office Action, p. 2). Applicants respectfully traverse this rejection.

The M.P.E.P. § 2163 states:

> To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention…Much of the written description case law addresses whether the specification as originally filed supports claims not originally in the application. The issue raised in the cases is most often phrased as whether the original application provides "adequate support" for the claims at issue or whether the material added to the specification incorporates "new matter" in violation of 35 U.S.C. 132...**In addition, early opinions suggest the Patent and Trademark Office was unwilling to find written descriptive support when the only description was found in the claims; however, this viewpoint was rejected.** See *In re Koller*, 613 F.2d 819, 204 USPQ 702 (CCPA 1980) (original claims constitute their own description); accord *In re Gardner*, 475 F.2d 1389, 177 USPQ 396 (CCPA 1973); *accord In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976). **It is now well accepted that a satisfactory description may be in the claims or any other portion of the originally filed specification**. (Emphasis added.)

The present application was filed on April 12, 2004, with claims 1-83 appended to the description. Present claims 1-37 currently under examination are original to the application. Because claims 1-37 are original to the application, the subject matter of these claims does not constitute new matter (M.P.E.P. § 2163, *supra*). This rejection should be withdrawn.

Rejection under 35 U.S.C. § 102(b) or 35 U.S.C. § 103(a)

The Office rejects claims 1-11, 13, 16-24, and 28-37 under 35 U.S.C. § 102(b) for anticipation by Wironen or, in the alternative, under 35 U.S.C. § 103(a) for obviousness over Wironen. The Office states that Wironen "discloses a bone paste comprising demineralized bone matrix (DBM) and calcium phosphate (see Abstract; page 6, lines 17-23)…The calcium phosphate component may be a mixture of various bioactive glass ceramic (see page 6, lines 20-23)" (Office Action, p. 4). The Office further states:

> Even if the reference does not anticipate the instant claims[, t]hose of ordinary skill would expect overlapping values for the claimed compression strength and Ca/P rations [sic:ratios] given that the same materials are found in the instant claimed bone past[e]. Further, since the instant bone paste is used for the same therapeutic purpose, there would be a reasonable expectation of similar therapeutic results. The instantly claimed osteoinductive composition would have therefore been obvious given the disclosure of [Wironen]." (Office Action, p. 5.)

Applicants have amended present independent claims 1 and 37, and claims dependent therefrom, to recite an osteoinductive powder that includes demineralized bone matrix (DBM) particles **in an amount in the range of about 40 to about 70 wt%**. Wironen fails to teach or suggest an osteoinductive powder having all of the limitations of claims 1, 3, 4, and 7-37, as presently amended, including the above-mentioned DBM wt% range limitation.

Wironen describes a bone paste that includes thermally sterilized gelatin and an osteogenic component having one or more of the following:

(i) demineralized bone, preferably derived from the species into which the thermally sterilized bone paste is to be implante; or
(ii) bioactive glass ceramic, BIOGLASS®, bioactive ceramic, calcium phosphate ceramic, hydroxyapatite, hydroxyapatite carbonates, corraline hydroxyapatite, calcine bone, cortical bone chips, cancellous bone chips, tricalcium phosphate, like material, or mixtures thereof; or
(iii) bone morphogenetic protein, osteogenic proteins or peptides (e.g.

osteogenin, p15, CDMP, and the like), TGF-beta, bone marrow extracts, vascular proliferation or regeneration growth factors, PDGF, or mixtures thereof, natural or recombinant; or

(iv) mixtures of (i)-(iii). (See p. 6, lines 18-27.)

With respect to the amount of DBM to be included in the bone paste, Wironen states:

> We have found in *in vivo* studies that the compositions with DBM contents from 15 to 33% all produce calcified tissue. We have found that there is a good correlation between the amount of DBM in the composition and the level of bone induction, as long as the DBM concentration is greater than about 19% (w/w). **About 38-40% (w/w) is the upper mass limit for DBM**. Accordingly, 1-40% (w/w) DBM, and more preferably 5-30% (w/w), 7-33% (w/w) or 15-25% (w/w) is desirable for this component. (Wironen, p. 16, line 28, through p. 17, line 2; emphasis added.)

Thus, Wironen not only fails to teach or suggest a composition that includes an amount of DBM within Applicants' claimed range of about 40 to about 70 wt%, as is recited in present claims 1, 3, 4, and 7-37, Wironen also teaches away from such a composition by instructing the reader to incorporate an amount of DBM within a completely different range (i.e., 5-40 wt%; see p. 16, lines 18-19). Accordingly, the osteoinductive powder of present claims 1, 3, 4, and 7-37 is nonobvious over Wironen (M.P.E.P. § 2144.05(III); "A prima facie case of obviousness may be rebutted by showing that the art, **in any material respect**, teaches away from the claimed invention. *In re Geisler*, 116 F.3d 1465, 1471, 43 USPQ2d 1362, 1366 (Fed. Cir. 1997)"; emphasis added. *See also In re Gurley*, 31 USPQ2d 1130, 1132, 27 F.3d 551, 553 (Fed. Cir. 1994) ("A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant.") and *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1739–40 (2007) (explaining that a reference teaches away when a skilled artisan, upon reading the reference, would be led on a divergent path from the one taken by the Applicants and when the prior art teaches away from a combination, that

combination is more likely to be nonobvious)).

In addition,Wironen fails to teach or suggest a composition that includes a calcium phosphate component that hardens to form a poorly crystalline apatitic (PCA) calcium phosphate upon the addition of a physiologically acceptable liquid, much less a composition that, when hardened, has a compressive strength of greater than at least about 1 MPa, as is recited by present claims 1, 3, 4, and 7-37.

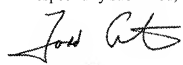
Because Wironen fails to teach or suggest each and every limitation of present claims 1, 3, 4, and 7-37, Applicants respectfully request that the rejection of claims 1-11, 13, 16-24, and 28-37 under 35 U.S.C. §§ 102(b) and 103(a) for obviousness over Wironen be withdrawn.

CONCLUSION

In view of the above remarks, Applicants respectfully submit that the present claims are in condition for allowance, and such action is respectfully requested.

A petition to extend the period for replying for one month, to and including October 20, 2008, is submitted herewith. Applicants authorize the Office to deduct the fee required by 37 C.F.R. § 1.17(a) from Deposit Account No. 03-2095 for the petition. Applicants also authorize the Office to deduct the excess claims fee of $104.00 for four claims beyond the number of claims for which fees have already been paid. If there are any additional charges, or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,



Todd Armstrong, Ph.D.
Reg. No. 54,590

Date: 20 October 2008

for Paul T. Clark
Reg. No. 30,162

Clark & Elbing LLP
101 Federal Street
Boston, MA 02110
Telephone: 617-428-0200
Facsimile: 617-428-7045